NOV 0 6 2001

K013316

October 2, 2001

Sickle-Chex
510(k) Notification

Names

Trade Name	Sickle-Chex
Common Name:	Assayed Sickle Cell Control
Classification Name:	Sickle Cell Test, 21 CFR 864.7825
Classification Number:	Not Available

Establishment Registration Number

1950302

Classification

FDA has assigned Sickle Cell Test to Class II, performance standards.

Actions Taken to Comply with FDCA Section 154

No government mandatory or industry voluntary performance standards exist for this type of device.

Representative Labels and Labeling

Proposed vial labels and other labeling attached:

a. Package insert/ assay sheet
b. Vial labels (Table I)
c. Outer package labeling (Table I)

Predicate product package insert and assay sheet

Physical description of Device

Sickle-Chex consists of Control materials for verifying performance of sickle cell hemoglobin testing systems. The controls contain human red blood cells and preservative suspension media packaged in a polyethylene dropper bottle with dispensing tip. Product fill is 2.5 ml per vial.

Intended Use

Sickle-Chex consists of two controls. The Positive Control is a suspension of human red blood cells in a preservative media. This product is intended for use as a quality control material for sickling hemoglobin test kits. The Positive Control will produce a positive test for sickling hemoglobin using standard sickle cell hemoglobin solubility test reagents. In like manner, the Negative Control contains normal human red blood cells that will produce a negative test for sickling hemoglobin using standard sickle cell hemoglobin solubility test reagents.

Sickle-Chex may also be used as a control in hemoglobin electrophoresis methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Paul Kittelson
Quality Assurance/Regulatory Affairs
Streck Laboratories, Ins.®
7002 South 109th Street
LaVista, NE 68128

NOV 0 6 2001

Re: k013316
Trade/Device Name: Sickle-Chex
Regulation Number: 21 CFR 864.7825
Regulation Name: Sickle cell test
Regulatory Class: Class II
Product Code: GHM
Dated: October 3, 2001
Received: October 4, 2001

Dear Mr. Kittelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 6 2001

K013316

510(k) Number: K013316

Device Name: Sickle-Chex

Indications For Use: Sickle-Chex is intended to be used as a sickle cell control in testing for the presence of hemoglobin S in solubility tests and hemoglobin electrophoresis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Date: _____

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K013316